



IN DEFENSE OF ANIMALS

9800 '00 FEB 16 10:04

February 8, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 99D-5347

"Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Close Contacts"

To whom it may concern:

We feel the proposal to "indefinitely defer" blood donations from xenotransplantation recipients and their close contacts is warranted, but that the proposal is too dangerous to the public due to its inherent unworkability.

Such a proposal will satisfy those with a marginal understanding of the grave long-term risks to the public's health associated with trans-species organ donation, but the near certainty of oversight failure bears consequences impossible to over estimate. This proposal places the nation's blood supply at risk.

Attempting to keep track of every close contact of an animal organ transplant recipient is clearly unreasonable. With the best of intentions and the most sophisticated monitoring and registry, what people do in private, on their own time, and while traveling abroad, is simply impossible to control. Unless all such persons are incarcerated there can really be no guarantee of protection.

The general problem seems to be that safeguards are being proposed for unknown risks. If viruses are transmitted to humans from animal organ transplants, the viruses will be subjected to a new environment. Evolutionary biologists believe that environmental change is one of the engines of evolution. Since every recipient of an organ transplant is a unique physiological and biochemical environment we should expect multiple viral varieties to evolve. Exactly how these new viruses might be transmitted is impossible to predict. Moreover, which of these new viruses might be deadly is also impossible to predict.

Apparently an animal organ transplant recipient would be tracked for their entire life, as would their close contacts. So, a woman has a transplant and *her* husband will be registered. Will *his* female co-worker be tracked? *Her* husband? *His* female friends? It seems that even the obvious potential vectors would spiral into huge numbers of people who would require registry. Ignoring such associations would place the nation's blood supply at risk of contamination with the potential for a very nasty pandemic.

99D-5347

C15

The risks seem to be so poorly understood and the safeguards so woefully mistake prone that we must protest any animal to human organ transplantation. Xenotransplantation is a false hope. The health of millions of people worldwide should not be placed at risk just to pursue an unproven technology fraught with such extreme risk. The suggestions in the proposed guidelines are inadequate and will not protect the public health.

Xenotransplantation should be banned.

Research intended to advance xenotransplantation should be halted.

Sincerely,

A handwritten signature in black ink, appearing to read 'RB' or 'Rick Bogle', written in a cursive style.

Rick Bogle



IN DEFENSE OF ANIMALS

131 CAMINO ALTO, SUITE E
MILL VALLEY, CA 94941
(415) 388-9641



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

"It's a matter of
taking the side of
the weak against the
strong, something
the best people
have always done."
Harriet Beecher Stowe

20857/0001



Recycled Paper